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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,824	02/24/2000	Yasuo Yamao	FUJ2-AZ72a	5341
7590	04/26/2002			EXAMINER GABEL, GAILENE
Joseph W Price Price Gess & Ubell 2100 S E Main Street Suite 250 Irvine, CA 92614			ART UNIT 1641	PAPER NUMBER TJF
			DATE MAILED: 04/26/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/511,824	YAMAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on Interview Summary on 4/9/02.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 8,9,11 and 12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 8,9,11 and 12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>14</u> .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Prosecution Reopened***

1. Prosecution on the merits of this application is reopened on claims 9 and 11-12.

***Amendment Entry***

2. Applicants' amendment and arguments filed 1/22/02 in Paper No. 13 are acknowledged and have been entered. Claim 9 has been amended. Currently, claims 8-9 and 11-12 are pending and under examination.

***Rejection Withdrawn***

***Claim Rejections - 35 USC § 112***

3. In light of Applicant's amendment, the rejection of claims 9 and 11-12 under 35 U.S.C. § 112, second paragraph is hereby, withdrawn.

***Rejection Maintained***

***Claim Rejections - 35 USC § 103***

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (US 4,889,815) in view of Minoru et al. (JP 07-035752) and in further view of Hasegawa et al. (JP 06-265554) for reason of record.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 8 is rejected under 35 U.S.C. 102(b) as being clearly by Raffaele (US 4,013,417).

Raffaele et al. disclose a system comprising a means for lysing whole blood with a hemolysis reagent (lysing reagent or freeze-thaw method), means for reacting antigens in the blood (cuvette), means for measuring absorbance (spectrophotometer), and a means for determining and calculating results obtained (computer). See especially Abstract, columns 2-4, and claims 1 and 7.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 8-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (US 4,889,815) in view of Loretz (US 4,357,105).

Bradwell et al. disclose an immunoassay system comprising a means for lysing whole blood with a hemolysis reagent (cuvette made of transparent suitable material charged with lysing reagent such as saponin/KCN). The system further comprises a means for reacting antigens in the whole blood sample to form a reaction mixture comprising insoluble carriers with antibodies immobilized thereto (latex bound antibodies) (see column 3, lines 16-33). The system further includes a nephelometer for use in analysing the reactions in whole blood without the need to remove blood cells or hemoglobin (see column 1, lines 51-54). A second detector is included to compensate for the amount of light absorbed possibly by the hemoglobin in the sample to minimize and correct for any degree of absorption by the hemoglobin in the sample (see column 1, lines 21-25, 51-54; column 3, lines 16-54 ; column 4, lines 59-61). In the system, wavelength is read where the strength of radiation scattered by antigen/antibody complex is high and the absorption by hemoglobin and other proteins is low.

Bradwell et al. differ in failing to irradiate and measure the reaction product at a wavelength range that is substantially free from absorption by both hemoglobin and hemolysis reagent.

Loretz discloses a blood diagnostic spectrophotometer that performs hemoglobin determinations in blood. The spectrophotometer is capable of measuring turbidity in blood (see Abstract). Loretz uses saponin to hemolyze the whole blood (see column 2, lines 47-66). According to Loretz, blood turbidity can be determined by measuring at a wavelength that is near-infrared. Specifically, Loretz discloses that absorbance measurements of hemolyzed blood at or near infra-red range are substantially free from the absorbance of hemoglobin (see column 7).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to irradiate and measure the reaction product in the method of Bradwell, at a wavelength range that is free from absorption by hemoglobin as taught in the method of Loretz, because Bradwell specifically suggested determining analyte concentration at a wavelength range having minimal effect by hemoglobin and also correcting for any degree of absorption by hemoglobin in the sample, and Loretz specifically showed that absorbance at a wavelength range substantially free from effects of hemoglobin can be achieved, at or near infrared wavelength.

7. Claims 8-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (US 4,889,815) in view of Osten et al. (US 5,729,333).

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Bradwell et al. has been discussed supra. Bradwell et al. differ in failing to irradiate and measure the reaction product at a wavelength range that is substantially free from absorption by both hemoglobin and hemolysis reagent.

Osten et al. provide a method for characterizing properties of biological matter containing water by analyzing at near-infrared spectrum of the biological matter while in a dynamic condition. Osten et al. specifically disclose that absorbance of water in the 1150-1190 nm range is substantially free from the absorbance of hemoglobin both in its oxygenated state and deoxygenated state (see columns 3-4, especially column 4, lines 42-58).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to irradiate and measure the reaction product in the method of Bradwell, at a wavelength range that is free from absorption by hemoglobin as taught in the method of Osten, because Bradwell specifically suggested determining analyte concentration at a wavelength range having minimal effect by hemoglobin and also correcting for any degree of absorption by hemoglobin in the sample, and Osten specifically showed that absorbance at a wavelength range substantially free from effects of hemoglobin can be achieved, i.e. 1150-1190 in the case of biological matter containing water.

### ***Response to Arguments***

8. Applicant's arguments regarding claim 8 filed 1/22/02 have been fully considered but they are not persuasive.

A) Applicant argues that Bradwell et al. failed to irradiate and measure the reaction product at a wavelength range that is substantially free from absorption by both hemolysis and hemolysis reagent, using a means that measures at that wavelength, and both secondary references, Minoru and Hasegawa, fail to overcome the deficiency of Bradley or to suggest measuring at 800 nm which is free from absorption by both hemolysis and hemolysis reagent, in order to arrive at the teaching of the claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., measuring at 800 nm) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Alternatively, while none of Bradwell, Minoru, and Hasegawa suggest measuring the reaction product at 800 nm which is a wavelength free from absorption from hemolysis and hemolysis reagent, the combination of Bradwell, Minoru, and Hasegawa suggest using an immunoassay system comprising a spectrophotometer as a means for irradiating and measuring at any wavelength, including 800 nm, which is a wavelength level free from absorption of hemolysis and hemolysis reagent, because spectrophotometers inherently have the capability to make measurements of absorbance at any desired level, including those at or near infrared levels.

**Remarks**

9. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Goldberg et al. (US 3,569,721) disclose measuring the concentration of bilirubin in blood serum by defining the transmission of serum in terms of bilirubin concentration at two preselected specific wavelengths of light excluding the effect or interference by hemoglobin (see especially column 3).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Gailene R. Gabel  
April 25, 2002

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/511,824	YAMAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gailene R. Gabel	1641	

All participants (applicant, applicant's representative, PTO personnel):

(1) Gailene R. Gabel.

(3) \_\_\_\_\_.

(2) Joseph Price.

(4) \_\_\_\_\_.

Date of Interview: 24 April 2002.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 8,9,11 and 12.

Identification of prior art discussed: of record.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

#### **Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### **37 CFR §1.2 Business to be transacted in writing.**

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Indicated to Mr. Price on 4/9/02 that claims 9 and 11-12 are allowable but claim 8 fails to obviate the prior art. Mr. Price has notified Applicant of the current status of the claims. However, Applicant has not made a decision to date, to cancel claim 8. Mr. Price was notified that an Advisory Action would be forthcoming. However, upon further search, relevant prior art was found. Therefore, prosecution is reopened. Mr. Price was notified 4/24/02 that prosecution of claims 8-9 and 11-12 has been reopened.